

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

V.

IMPAX LABORATORIES, INC.,

Defendant.

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) Civil Action No.: 06-222 JJF
)
) **PUBLIC VERSION**
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**DEFENDANT'S BRIEF IN SUPPORT OF MOTION
TO COMPEL A RESPONSE TO INTERROGATORY NUMBER 35**

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I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff Wyeth (“Wyeth”) brought this action for patent-infringement to prevent Defendant Impax Laboratories, Inc. (“Impax”) from selling a generic version of Wyeth’s product EFFEXOR® XR, which is a formulation of the anti-depressant medication venlafaxine hydrochloride. A third party, Alza Corporation (“Alza”), has, in turn, sued Wyeth in the United States District Court for the Eastern District of Texas, claiming that Wyeth’s EFFEXOR® XR product infringes Alza’s patent on a method for administering an extended release venlafaxine formulation. In the instant litigation, Impax contends that the Alza patent is invalidating prior art.

In the course of discovery, Impax has learned that Wyeth and Alza had a joint-development agreement in the 1990s to develop extended release venlafaxine compounds using Alza’s technology. Documents produced by Wyeth indicate that some of the formulations developed by Alza are likely additional invalidating prior art to the patents asserted by Wyeth in the instant litigation.

Accordingly, Impax has propounded an interrogatory asking Wyeth to state whether the inventors of the patents-in-suit were aware of the Alza joint-development effort and Alza’s extended release venlafaxine formulations and the basis for any contention by Wyeth that this information was not material to patentability or that Wyeth did not intend to deceive the patent office in withholding this information. Wyeth has objected to this interrogatory as irrelevant and has refused to respond. Because this discovery is relevant to Impax’s defenses of invalidity and unenforceability, Impax brings this motion to compel a response to its Interrogatory No. 35.

II. FACTUAL BACKGROUND

A. Wyeth sues Impax for infringement of its patents claiming methods for administering extended release venlafaxine formulations.

Wyeth initiated this action against Impax on April 5, 2006 alleging patent infringement under 35 U.S.C. § 271(e)(2)(A) by reason of Impax’s submission to the

Food and Drug Administration (“FDA”) of Abbreviated New Drug Application (“ANDA”) No. 78-057.¹ D.I. 1. Impax filed its Answer and Counterclaims on April 25, 2006, denying infringement and asserting a defense and counterclaim that the patents-in-suit are invalid pursuant to 35 U.S.C. §§ 101 *et seq.* D.I. 7. Impax filed its First Amended Complaint on August 10, 2006 asserting an additional defense and counterclaim that the patents-in-suit are unenforceable for inequitable conduct. D.I. 33.

The patents-in-suit claim an “extended release formulation” of the antidepressant medication venlafaxine hydrochloride and methods for administering this extended release formulation. *See, e.g.*, ‘171 patent, Abstract, Cls. 1, 21. Wyeth’s patents claim a very specific “extended release formulation” defined as:

a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroid are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.

‘171 Patent, Cl. 1. Wyeth has accused Impax of infringing its claims on methods for administering this extended release formulation.

B. Alza sues Wyeth for infringement of its patent claiming a method for administering extended release venlafaxine formulations.

Wyeth itself has been sued by Alza in the Eastern District of Texas. *See* Declaration of Mary B. Matterer in Support of Impax’s Motion to Compel (“Matterer Decl.”), Ex. 1. In that litigation, Alza claims that Wyeth’s EFFEXOR® XR product infringes Alza’s U.S. Patent No. 6,440,457 (“the Alza Patent”). Like the patents-in-suit, the Alza Patent claims a method of administering extended release venlafaxine hydrochloride. *Id.*, Ex. 1 at 14, Cl. 1.

¹ The patents-in-suit are U.S. Patent No. 6,274,171 (“‘171 patent”), U.S. Patent No. 6,403,120 (“‘120 patent”), and U.S. Patent No. 6,419,958 (“‘958 patent”).

In the instant litigation, Impax has asserted the Alza Patent as invalidating prior art, because the patents-in-suit appear to be nothing more than a specific embodiment of Alza's claimed invention. Certainly if Wyeth's improbable construction of the term "extended release formulation" were adopted – that it is not limited to the specific formulation plainly defined in Claim 1 of the '171 Patent – the Alza patent would anticipate some or all of Wyeth's method claims.

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(Footnote continued)

In addition, as a result of its research, Alza submitted a PCT patent application, WO 94/27589. Matterer Decl., Ex. 5 (“Alza’s PCT Application”). Alza’s PCT Application publicly discloses extended release venlafaxine formulations that Impax will contend anticipate one or more of the asserted claims of the patents-in-suit. In disclosing these formulations, the Alza PCT Application does not explicitly disclose the limitations of the asserted claims that the methods “eliminate[] the troughs and peaks of drug concentration in a patient’s blood plasma” or “provide[] a peak blood plasma level of venlafaxine in from about 4 to about 8 hours.” *See, e.g.*, ‘958 Patent, Cl. 2. But Impax will prove that these limitations are inherently anticipated by the formulations disclosed in the PCT Application.

D. Wyeth refuses to respond to interrogatories regarding the Alza formulations.

In light of these discoveries, Impax posed interrogatories to Wyeth regarding its collaboration with Alza and the Alza extended release venlafaxine formulations.

Impax’s Interrogatory No. 35 asks Wyeth to state its contention as to whether Wyeth or the inventors of the patents-in-suit were aware of Alza’s development of an extended release formulation:

To the extent WYETH contends that, during the prosecution of the PATENTS IN SUIT, WYETH or the NAMED INVENTORS were not aware of ALZA’s development of an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE beyond the disclosure in publication WO 94/27589, that the information known about ALZA’s development was not material to patentability, and/or that information known about ALZA’s development was not withheld from the PTO with the intent to deceive, IDENTIFY all factual and legal bases for such contentions, including all PERSONS who have knowledge of such bases,

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what knowledge each PERSON has, and all DOCUMENTS that evidence such bases, for WYETH's contentions.

Matterer Decl., Ex. 4 at 12, Interrogatory No. 35.

Wyeth refused to respond to this interrogatory. Matterer Decl., Ex. 6 at 41-42, Response No. 35.

Impax has met and conferred with Wyeth extensively in order to get a response to this interrogatory. Impax first wrote to Wyeth on October 30, 2006. Matterer Decl., Ex. 7 at 3. In subsequent telephonic meet and confers, Wyeth contended that the interrogatory is irrelevant.

On November 27, 2006, Impax proposed a compromise, asking that Wyeth answer the narrower question, "[d]oes Wyeth contend that the named inventors of the patents-in-suit were unaware of Alza's development of an extended release formulation comprising venlafaxine beyond the disclosure in publication WO 94/27589?" Matterer Decl., Ex. 8 at 2. Wyeth rejected this compromise, contending that "[t]he question posed in your November 27th letter is not relevant to any issue in this case." *Id.*, Ex. 9 at 3.

The Parties exchanged Amended Interrogatory responses on January 10, 2007, but Wyeth still did not respond to Interrogatory No. 35. On January 29, 2007, Impax wrote a final letter to Wyeth, stating, "[w]e strongly disagree with Wyeth's refusal to respond to these interrogatories. The agreements Wyeth had with Alza and the persons at Wyeth aware of the Alza prior art are relevant to Impax's invalidity defense based on the Alza prior art." Matterer Decl., Ex. 10 at 2.

Half an hour before the close of business on Friday, February 2, 2007, after Impax had already prepared this motion, Wyeth faxed Impax a letter stating that it would agree to answer a much narrower question than that posed in the interrogatory: "Does Wyeth contend that as of March 25, 1996, the named inventors were unaware that Alza was attempting to formulate a formulation comprising venlafaxine hydrochloride?" Matterer Decl., Ex. 11.

Impax responded that this narrower question did not provide the information Impax requires because Impax requires information regarding whether the inventors of the patents-in-suit were aware of the Alza prior art formulations *at any time*, including throughout the time when the patents-in-suit were in prosecution. Matterer Decl., Ex. 12. On February 5, 2007, Impax specifically offered to limit the interrogatory to the period ending with the issuance of the last patent, July 16, 2002. This offer was rejected. Matterer Decl., Ex. 13 at 2. Impax needs to identify Wyeth witnesses for deposition who had knowledge of the Alza prior art, regardless of whether they had knowledge prior to 1996.

This motion to compel followed.

III. ARGUMENT

A. **Discovery regarding Alza's development of an extended release venlafaxine formulation is relevant to Impax's defense of invalidity.**

1. **Alza's extended release venlafaxine formulations are potentially invalidating prior art.**

Pursuant to Rule 26(b)(1), “[p]arties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party.” This Court has further held that “discovery should ordinarily be allowed under the concept of relevancy unless it is clear that the information sought can have no possible bearing upon the subject matter of the action.” *In re Intel Corp. Microprocessor Antitrust Litigation*, 2007 WL 137152, *5 (D.Del. 2007) (quoting *La Chemise Lacoste v. Alligator Co., Inc.*, 60 F.R.D. 164, 171 (D.Del.1973)).

Impax is entitled to take discovery from Wyeth regarding the extended release venlafaxine formulations Alza developed because this information is relevant to Impax's invalidity defense based on the Alza formulations. These formulations are likely invalidating prior art, either alone, or in combination with other prior art.

There are at least four sections of the patent act under which these prior art formulations may be invalidating prior art.

First, under 35 U.S.C. § 102(b), a patent claim is invalid if “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” Impax contends that at least claim 2 of the ‘958 patent is invalid under this section, in light of the formulations disclosed in Alza’s PCT Application.³ Impax’s contention is that one or more of these formulations inherently anticipate the limitations of claim 2 regarding “eliminating the troughs and peaks of drug concentration in a patient’s blood” and “provid[ing] a peak blood plasma level of venlafaxine in from about 4 to about 8 hours.” ‘958 Patent, Cl. 2.

Second, under 35 U.S.C. § 102(a), the claims of the patents-in-suit are invalid if “the invention was known or used by others in this country . . . before the invention thereof by the applicant for patent.” If, as the documents produced by Wyeth indicate, Alza produced formulations that anticipate one or more claims of the patents-in-suit, the inventions disclosed in one or more of the asserted claims were “known and used by others in this country.”

Third, under 35 U.S.C. § 102(f), the claims of a patent are invalid if the named inventor “did not himself invent the subject matter sought to be patented.” If, as Impax contends, Alza developed formulations and methods for using the formulations that Wyeth claims in the patents-in-suit, then the inventors on the face of the patents-in-suit did not invent the subject matter disclosed in the patents, and one or more of the claims are invalid under this section.

³ The Alza PCT Application published internationally on December 8, 1994, which is more than one year prior to the March 1996 date Wyeth contends is the priority date for the patents-in-suit.

Fourth, under 35 U.S.C. § 102(g)(2), the claims of a patent are invalid if before [the patentee's] invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.

Impax seeks to prove in the instant litigation that Alza did make one or more of the alleged inventions disclosed in the patents-in-suit, thereby rendering one or more of the claims of the patents-in-suit invalid under this section.

Accordingly, discovery regarding the extended release venlafaxine formulations that Alza made under its collaboration with Wyeth is relevant to Impax's claim that "[t]he Patents-in-Suit and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to . . . anticipation [and] obviousness . . . in accordance with 35 U.S.C. §§ 102 [and] 103." (D.I. 33 at ¶ 46).

Because discovery regarding the Alza prior art is plainly relevant to Impax's invalidity defense, Wyeth must provide a full, substantive response to Interrogatory No. 35.

2. Impax is entitled to discover the identity of persons at Wyeth having knowledge of the Alza prior art formulations.

Nonetheless, Wyeth has refused to respond to Impax's Interrogatory regarding whether the inventors of the patents-in-suit had knowledge of the Alza formulations under an objection that such discovery is "irrelevant to any issue in the suit and not reasonably calculated to lead to the discovery of admissible evidence." *Id.*, Ex. 6 at 42, Objection to Interrogatory No. 35.

The identity of persons at Wyeth who have knowledge of the Alza collaboration and prior art Alza formulations – including the inventors – is highly relevant and subject to discovery pursuant to Rule 26. Rule 26(b)(1) specifically provides that parties may obtain discovery regarding "the identity and location of persons having knowledge of any

discoverable matter.” Fed. R. Civ. P. 267(b)(1). Hence, in *Scripps Clinic and Research Foundation v. Baster Travenol Laboratories, Inc.*, 1988 WL 70013 (D. Del. June 21, 1988), this Court compelled a patent holder to respond to interrogatories requiring it to identify “everyone who was consulted in order to answer the interrogatories, as well as everyone who had control or custody of any documents produced in response to the interrogatories.” *Id.* at *2. As Wyeth has done here, the patent holder objected to the interrogatories “as seeking irrelevant information.” *Id.* The Court rejected these objections, holding that the “requests fall squarely within the scope of this Rule [26(b)(1)] and must be answered.”

Similarly, here, the identity of all Wyeth employees – including the inventors – having knowledge of the Alza formulations falls squarely within the scope of discovery afforded by Rule 26(b)(1). Impax requires this information in order to identify witnesses to depose regarding these potentially invalidating formulations. These witnesses will have information regarding the ingredients of those formulations, who developed the formulations, and other details regarding the formulations that may bear on the invalidity of the patents-in-suit.

Because the question of whether the inventors of the patents-in-suit had knowledge of the Alza formulations and agreements is relevant to Impax’s defense and counterclaim of invalidity, the Court should compel Wyeth to answer Interrogatory 35.

B. Wyeth’s knowledge of Alza’s prior art formulations is relevant to the unenforceability of the patents.

Interrogatory No. 35 is further relevant to Impax’s defense and counterclaim that the patents-in-suit are unenforceable. (D.I. 33 ¶¶ 85-94). Although Wyeth cited to the PTO the Alza PCT Application, it failed to cite to the PTO the fact of the Alza

collaboration and the formulations Alza developed during this collaboration. This information was material to patentability under any standard of materiality.⁴

First, Impax contends that the Alza prior art “establishes, by itself or in combination with other information, a prima facie case of unpatentability.” 35 C.F.R. § 1.56(b)(1) (cited in *Digital Control Inc.* 437 F.3d at 1315).

Second, Impax contends that the Alza prior art “refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.” 35 C.F.R. § 1.56(b)(2) (cited in *Digital Control Inc.* 437 F.3d at 1315).

Third, the Alza prior art is material under the common law test that “a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application.” *Digital Control*, 437 F.3d at 1314 (quoting *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed. Cir. 2003)).

Wyeth contends that it is not obligated to answer this interrogatory because Impax has not yet pled with particularity its theory of inequitable conduct based on the withholding of the Wyeth prior art. But Impax requires this discovery in order to gather the information required to plead this theory of inequitable conduct with particularity. Under Wyeth’s construction of Rule 26, a party would seldom be able to plead inequitable conduct with particularity, because a party could never discover information regarding that claim until it had already pled the claim with particularity.

This is not the law. As this Court has observed, “discovery should ordinarily be allowed under the concept of relevancy unless it is clear that the information sought can have no possible bearing upon the subject matter of the action.” *In re Intel Corp*, 2007

⁴ In *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006), the Federal Circuit established that materiality can be demonstrated under both the standards promulgated by the Patent and Trademark Office or under the common law standard.

WL 137152 at *5. Impax has raised the subject matter of the unenforceability of the patents-in-suit in its amended answer, and it is permitted under Rule 26 to take discovery on that topic.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Impax's motion to compel a response to Interrogatory No. 35.



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